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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/039,743 | 10/26/2001 | Balakrishnan Shankar | SJ1-026US | 9121 |

7590

10/10/2003

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| EXAMINER |
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OROEPEZA, FRANCES P

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| ART UNIT | PAPER NUMBER |
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3762

DATE MAILED: 10/10/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/039,743

Applicant(s)

SHANKAR ET AL.

Examiner

Frances P. Orop za

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/26/01 (Initial Filing).
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-64 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-26, drawn to an implantable cardiac therapy device with therapy circuit, classified in class 607, subclass 4.
 - II. Claims 27-33, drawn to an implantable cardiac therapy device comprising a diplexer, classified in class 607, subclass 60.
 - III. Claims 34-41, drawn to implantable cardiac therapy device comprising a header with a first and a second conductive feed-throughs, classified in class 607, subclass 36.
 - IV. Claims 42-47, drawn to an implantable cardiac therapy device comprising a cardiac management means for managing cardiac activity, classified in class 607, subclass 3.
 - V. Claims 48-52, drawn to a cardiac therapy system comprising a programmer, classified in class 607, subclass 30.
 - VI. Claims 53-58, drawn to a cardiac network system comprising a computing network, classified in class 607, subclass 32.
 - VII. Claims 59-64, drawn to a method for receiving high and low frequency signals using isolated regions, classified in class 607, subclass 36.

The inventions are distinct, each from the other because of the following reasons:

Inventions I. and II. are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require a header. The subcombination has separate utility such as an implantable cardiac therapy device not requiring a casing to house both cardiac therapy and the communication circuitry (claim 1)/ a first and as second chamber/ can to isolate the communication circuitry from the cardiac therapy circuit (claims 10 and 19), but rather using an EMI-resistant chamber for the cardiac therapy circuitry and isolating the RF circuitry from the cardiac therapy circuitry.

Inventions I. and III. are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require a header with first and second conductive feed-throughs. The subcombination has separate utility such as an implantable cardiac therapy device not requiring a cardiac therapy unit to monitor cardiac activity or administration therapy but rather a cardiac therapy device to provide therapy (such as by administering drug therapy).

Inventions IV. and I. are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require

the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require a cardiac therapy circuit to administer stimulation therapy. The subcombination has separate utility such as an implantable cardiac therapy device not requiring a cardiac management means to manage cardiac activity (such as by administering drug therapy or recording data), but rather using a cardiac therapy circuitry to perform at least one of cardiac activity monitoring or therapy administration.

Inventions III. and II. are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require an EMI resistant chamber for the cardiac therapy circuit. The subcombination has separate utility such as an implantable cardiac therapy device not requiring conductive feed-throughs to facilitate connection between the leads and the circuits (the RF circuit and the cardiac therapy circuit), but rather using a diplexer to enable communication between the leads and circuits (the cardiac therapy circuit and the communication circuit).

Inventions IV. and II. are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the

subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require a diplexer. The subcombination has separate utility such as an implantable cardiac therapy device not requiring a casing means to hold the cardiac management means and the communication means in frequency isolation, but rather using an EMI-resistant chamber for the cardiac therapy circuitry and isolating the RF circuitry from the cardiac therapy circuitry.

Inventions IV. and III. are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require a header, or a first and a second feed-throughs. The subcombination has separate utility such as an implantable cardiac therapy device not requiring a cardiac management means to manage cardiac activity (such as by administering drug therapy or recording data), but rather a cardiac therapy unit to perform cardiac therapy (such as by administering stimulation therapy).

Inventions I., II., III., and IV. and invention V. are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combinations as claimed do not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combinations as claimed do not require the

particulars of the subcombination as claimed because the combinations do not require a programmer. As to the inventions I., II. and III., these subcombinations have separate utility such as an implantable cardiac therapy device not equipped with a high-frequency transceiver to communicate with the programmer, but rather the implantable cardiac therapy device communicating with a non- programmer device (such as another implantable device to store collected data). As to invention IV., the subcombination has separate utility such as an implantable cardiac therapy device not equipped with a high-frequency transceiver to communicate with the programmer, but rather the implantable cardiac therapy device communicating with an external system to collect data.

Inventions VI. and inventions I., II., III., IV. and V. are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombinations as claimed for patentability, and (2) that the subcombinations have utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require a casing (invention I.)/ header (invention II.)/ housing (invention III.)/ casing means(invention IV.)/ programmer (invention V.). As to inventions I., II., III., IV. and V., these subcombinations have separate utility such as an implantable cardiac therapy device not linked to a computing system to receive data, but rather providing a communication circuitry (inventions I.)/ RF circuitry (invention II. and III.)/ communication means (invention IV.) / high frequency transceiver (invention V.) using high frequency signals to link the implantable cardiac therapy device with,

Art Unit: 3762

for example, other implanted devices, external/ internal data storage units, or a non-computer programmer.

Inventions VII. and inventions I., II., III., IV., V. and VI. are related as process and apparatuses for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatuses or by hand, or (2) the apparatuses as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus of inventions I., II., III., IV., V. and VI. can be used to practice the process of therapeutic electrical stimulation of cardiac tissue to create a regular cardiac rhythm or to provide treatment to correct irregular cardiac activity.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

The Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza whose telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 306-4520 for regular communication and (703) 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

10/6/03

Angela D. Sykes

ANGELA D. SYKES
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